

### **REMARKS**

With entry of this amendment, claims 15-17, 22-23 and 30-32 are pending. The claims have been amended to be directed to enteric administration and further clarify that the active ingredient is protected from absorption and/or degradation prior to entry into the intestine. Support for the amendment can be found in the specification at page 5, beginning at line 15. No new matter has been added.

#### **Rejection under 35 U.S.C. §102**

Claims 15-17, 23 and 27-30 were rejected under 35 USC § 102(e) as being anticipated by Focke et al. (USP 7,244,432). To the extent that this rejection may be considered applicable to the present claims, it is traversed for the following reasons.

The Examiner has taken the position that Focke et al., under the broadest reasonable interpretation, discloses enteric administration. Although Applicants disagree with this interpretation, in order to advance prosecution, independent claims 15 and 31 have been amended to specify that the active ingredient is protected from absorption and/or degradation prior to entry into the intestine. This feature is not disclosed by Focke et al.

Enteric formulation is a form which is prepared for absorption in the intestine. The term "oral administration" in Focke et al. defines only the route of administration, not the location where absorption occurs. Typically, oral administration formulations are tablets and the like which dissolve in the stomach. In contrast thereto, and as described in the specification, enteric administration is a special pharmaceutical formulation that protects the active ingredient until it enters the intestine. In other words, although Focke et al. describes oral administration, they do not disclose or render obvious a specific formulation which avoids absorption and/or degradation prior to entry into the intestine.

Claims 15-17, 23, and 27-32 were rejected under 35 USC § 102(b) as being anticipated by Tanabe et al (BBRC 223:492, 1996). To the extent that this rejection may be considered applicable to the present claims, it is traversed for the following reasons.

It is the Examiner's position that Tanabe et al. teach a pharmaceutical composition comprising a mixture of hydrolyzed peptides. However, Applicants respectfully submit that Tanabe et al. fail to disclose a pharmaceutical formulation which avoids absorption and/or degradation prior to entry into the intestine. Accordingly, Tanabe et al. fail to teach each and every element of the claimed invention. Reconsideration and withdrawal of the rejection are respectfully requested.

Rejections under 35 U.S.C. §103

Claims 15-17, 22, 23 and 27-30 were rejected under 35 USC § 103(a) as being unpatentable over Focke et al. and Marx (USP 5,898,037). To the extent that this rejection may be considered applicable to the present claims, it is traversed for the following reasons.

The Examiner continues to take the position that the birch tree allergen of Focke et al. reads on the present claims. Applicants respectfully disagree. The present claims require a mixture of peptides obtainable by hydrolysis, this mixture being neither disclosed nor suggested by Focke et al. Furthermore, the claims are specifically directed to an enteric formulation, which is not taught by Focke et al., as detailed above. The Marx patent fails to remedy this omission. Accordingly, the combination fails to teach each and every element of the invention. Reconsideration and withdrawal of the rejection are respectfully requested.

Claim 22 was rejected under 35 USC § 103(a) as being unpatentable over Tanabe et al. and Marx (USP 5,898,037). To the extent that this rejection may be considered applicable to the present claims, it is traversed for the following reasons.

As detailed above, Tanabe et al. fails to teach each and every element of the independent claims, namely an enteric formulation which is protected from absorption and/or degradation prior to entry into the intestine. The secondary reference, Marx, fails to remedy this omission.

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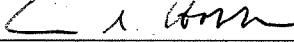
Accordingly, the combination fails to teach each and every element of the invention.

Reconsideration and withdrawal of the rejection are respectfully requested.

In view of the above amendment, applicant believes the pending application is in condition for allowance. If any issues remain that might be resolved by a telephonic examiner interview, the Examiner is invited to contact the undersigned.

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Respectfully submitted,

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